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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/727,718 | 11/30/2000 | Julian Van Erlach | XILL-3095 | 4074 |
| 5409 | 7590 | 08/25/2004 | EXAMINER | |
| ARLEN L. OLSEN SCHMEISER, OLSEN & WATTS 3 LEAR JET LANE SUITE 201 LATHAM, NY 12110 | | | SMITH, RUTH S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3737 | |
| DATE MAILED: 08/25/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/727,718 | Applicant(s) ERLACH ET AL. | |
| | Examiner Ruth S Smith | Art Unit 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 24 May 2004.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1,3-6,8,9 and 11-24 is/are pending in the application.

4a) Of the above claim(s) 20-24 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1,3-6,8,9 and 11-19 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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PTOL-326 (Rev. 1-04)

Office Action Summary

Part of Paper No./Mail Date 20040823

Art Unit: 3737

Election/Restrictions

Newly submitted claims 20-24 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The method set forth is not directed to a diagnostic method of a device placed in the body and can have industrial applicability

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-24 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

Claim 3 is objected to because of the following informalities: It is unclear as to whether the step of inserting is part of the step of encapsulating or a completely different step. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,6,9,15 are rejected under 35 U.S.C. 102(b) as being anticipated by Benjamin et al ('825). Benjamin et al disclose a method and system for injecting a microdevice into the vascular system or encapsulated into a cell (column 15, lines 33-34). Benjamin et al disclose using a microdevice carrying circuits for signal processing, the circuits containing silicon, phosphorus, providing output and transmitting information. It should be noted that while Benjamin et al disclose the use of white blood cells, the disclosure on lines 33-34 of column 15 does not preclude the use of other cell types.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,3,5-6,8,9,14,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin et al ('825). Benjamin et al disclose a method and system for injecting a microdevice into the vascular system or encapsulated into a cell (column 15, lines 33-34). Benjamin et al disclose using a microdevice carrying circuits for signal processing, the circuits containing silicon, phosphorus, providing output and transmitting information. It should be noted that while Benjamin et al disclose the use of white blood cells, the disclosure on lines 33-34 of column 15 does not preclude the use of other cell types such as red blood cells. The use of a white blood cell is merely an example disclosed by Benjamin et al. It would have been obvious to one skilled in the art that the method of Benjamin et al would be applicable to any type of cell that can be placed in vivo.

Art Unit: 3737

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin et al ('825) in view of Kopelman et al. Benjamin et al disclose a method and system for injecting a microdevice into the vascular system or encapsulated into a cell (column 15, lines 33-34). Benjamin et al disclose using a microdevice carrying circuits for signal processing, the circuits containing silicon, phosphorus, providing output and transmitting information. It should be noted that while Benjamin et al disclose the use of white blood cells, the disclosure on lines 33-34 of column 15 does not preclude the use of other cell types. Kopelman discloses inserting a microdevice or nanodevice into a cell using a known particle delivery system such as a particle gun injector. It would have been obvious to one skilled in the art to have modified Benjamin et al such that the means used to insert the device into a cell is a particle gun injector. Such a modification merely involves the selection of one well known means for providing for insertion of the device into a cell.

Claims 11,12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin et al in view of Ostensen et al. Benjamin et al disclose a method and system for injecting a microdevice into the vascular system or encapsulated into a cell (column 15, lines 33-34). Benjamin et al disclose using a microdevice carrying circuits for signal processing, the circuits containing silicon, phosphorus, providing output and transmitting information. It should be noted that while Benjamin et al disclose the use of white blood cells, the disclosure on lines 33-34 of column 15 does not preclude the use of other cell types. Ostensen et al disclose microparticles circulating in a body and detectable by magnetic resonance for medical diagnosis. It would have been obvious to one skilled in the art to have further modified Benjamin et al such that it is a resonance type nanodevice that is detected by magnetic resonance. Such a modification merely incorporates a well known technique for following the course of a device placed within the body.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin et al in view of Ostensen et al as applied to claim 12 above, and further in

Art Unit: 3737

view of Chandrakumar et al. Ostensen et al disclose microparticles circulating in a body and detectable by different imaging modalities for medical diagnosis. EPR is one well known type of imaging modality. It is known, as disclosed by Chandrakumar et al to use EPR imaging whereby the molecules detected comprise transition metal complexes. It would have been obvious to one skilled in the art to have further modified Benjamin et al such that EPR is used to detect the presence of the device in the body. Such a modification merely incorporates a well known technique for following the course of a device placed within the body.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin et al in view of Schechter. Benjamin et al disclose a method and system for injecting a microdevice into the vascular system or encapsulated into a cell (column 15, lines 33-34). Benjamin et al disclose using a microdevice carrying circuits for signal processing, the circuits containing silicon, phosphorus, providing output and transmitting information. It should be noted that while Benjamin et al disclose the use of white blood cells, the disclosure on lines 33-34 of column 15 does not preclude the use of other cell types. Schechter discloses the treatment of devices placed within a body with a compound to improve biological function by reducing antigenicity and prolonging retention by the host. It would have been obvious to one skilled in the art to have further modified Benjamin et al such that the device is treated with a material to prolong retention in the body in order to prolong its use.

Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin et al in view of Dustin et al or Li et al. Benjamin et al disclose a method and system for injecting a microdevice into the vascular system or encapsulated into a cell (column 15, lines 33-34). Benjamin et al disclose using a microdevice carrying circuits for signal processing, the circuits containing silicon, phosphorus, providing output and transmitting information. It should be noted that while Benjamin et al disclose the use of white blood cells, the disclosure on lines 33-34 of column 15 does not preclude the use of other cell types. Dustin et al disclose the use of lipid anchors to enable the

Art Unit: 3737

attachment of circulating micelles to a variety of target molecules on a cell.

Furthermore, it is well known in the art that organo hydroxyls (e.g. ethylene glycol) are used as cross-linking molecules that can be modified to have little effect on the chemistry of the molecules being linked. Li et al disclose the use of ethylene glycol as a lipid anchor to enhance the attachment of circulating microparticles to reduce clearance by the reticuloendothelial system and thereby increase the medical effectiveness of the microparticles. Therefore, it would have been obvious to one skilled in the art to have modified the device such that it includes a lipid anchor to promote attachment of the device to a cell and thereby prolong its presence in a body and enhance its diagnostic or therapeutic function.

Response to Arguments

Applicant's arguments filed May 24, 2004 have been fully considered but they are not persuasive. It should be noted that while Benjamin et al disclose the use of white blood cells, the disclosure on lines 33-34 of column 15 does not preclude the use of other cell types such as red blood cells. The use of a white blood cell is merely an example disclosed by Benjamin et al. It would have been obvious to one skilled in the art that the method of Benjamin et al would be applicable to any type of cell that can be placed in vivo. The examiner does not agree with applicant's reasoning regarding the use of other types of cells. If Benjamin were limited to white blood cells, the reference would clearly set forth that only white blood cells are to be used. Applicant's arguments regarding Ostensen et al are not understood. It should be noted that Chandrakumar was merely used as a teaching to show that it is known to use EPR as an imaging modality. It appears that applicant is arguing each reference individually. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Art Unit: 3737

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ruth S Smith
Primary Examiner
Art Unit 3737

RSS